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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,899	03/31/2004	John Riley Hawkins	3518.1001-001	1803
21005	7590	02/16/2006		
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			EXAMINER AMARELD JR, ROBERT W	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	10/813,899		HAWKINS ET AL.	
	Examiner		Art Unit	
	Robert W. Amareld, Jr.		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 14-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 12 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the method of implanting, claims 1-13 in the reply filed on 1/13/06 is acknowledged.

Claims 14-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/13/06.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "pin insertion instrument" in claim 8. There is insufficient antecedent basis for this limitation in the claim.

Specification

The disclosure is objected to because of the following informalities:

The attempt to incorporate subject matter into this application by reference to Appl # 10/011264, now US Pat#6755841 is ineffective because the referenced application also incorporates by reference in itself and it is inappropriate practice to incorporate by reference a reference which in itself incorporates by reference. See 37 CFR 1.57(c), partially restated here:

(c) “ Essential material ” may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference.

The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

Claim Objections

Claims 12 & 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Baynham (US Pat# 6224599). Baynham discloses a method of fixing a midline marker (104) to a face of a vertebral body as shown in Figure 5.

Claims 1, 2, 5-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Robie (US Pub# 20020161366, Appl# 10035863). Robie attaches the template (50) to a vertebral body as a midline marker, where the midline marker (50) is inserted in the guide of figure 4a and impacted until embedded with the vertebral body (P0058). An artificial disc (Hedrocel ALIF) is selected for implantation verified, where the size is verified by the insertion depth of the distractor (P0060), shown in Figure 10 and the implant is prepared for implantation (0061) by stuffing the implant with autologous bone. A window is removed from the annulus, where the window is the width of an artificial implant (P0052) and the nucleus pulposus is removed, as is inherent in the discectomy (P0053). For the purposes of claims 7, the distractors (10) will be trial spacers that are changed until an appropriate size is determined (P0056). The endplates are shaped by a reamer instrument (P0059), reamer instruments having blades, where the shaping instrument is guided by the midline marker (50) (P0059). The template is finally removed (P0063). As per claim 8, the trial spacers (10) are contacted by an insertion tool with a pin end (Figure 3B), where the template (50) (midline marker) is inserted with the pin insertion instrument of Figure 4A where the insertion instrument is removed as per the method figures 5-12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 & 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robie (US Pub#20020161366) in view of Michelson (UP Pub# 20020058944, Appl# 09972560). Robie is discussed supra. However Robie does not disclose radiographical markers. Michelson teaches radiographical (P0069) in the same field of endeavor or the analogous art of surgery for the purpose of radiographical imaging. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of radiographical markers, as taught by Michelson, to aid in radiographical visualization as per Robbie, in order to assure the implant is aligned properly and to verify the implant.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yonemura, Us Pat# 6086595 –spinal stabilization; Michelson, US Pat# 6224607 – intervertebral space.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am -5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone

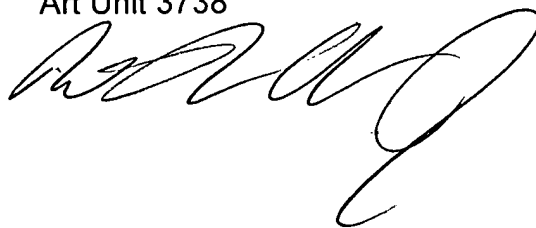
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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RWA

Robert W Amareld, Jr.
Examiner
Art Unit 3738



BRIAN E. PELLEGRINO
PRIMARY EXAMINER